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IN THE

Supreme Court of the United States

OCTOBER TERM 1991

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MINAS H. PAPAS, et al.,

Petitioners,

vs.

ZOECON CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITIONER'S REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

Dana G. Bradford, II
(Counsel of Record)
Lee S. Haramis
BAUMER, BRADFORD, WALTERS & LILES, P.A.
225 Water Street, Suite 2000
Jacksonville, Florida 32202
904/358-2222

Arthur H. Bryant
TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C.
1625 Massachusetts Ave., NW
Suite 100
Washington, D.C. 20036
202/797-8600

Attorneys for Petitioners

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INTRODUCTION

While Zoecon's Brief in Opposition attempts to dispute certain facts of this case[1], what is of far greater significance is its complete failure to dispute any of the legal issues presented by this appeal. Rather, Zeocon acknowledges that there is a direct split in the circuits and wide diversity of opinion in the lower and state courts, on the issue

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[1]Where pertinent, Petitioners will address certain incorrect factual assertions set forth in Zoecon's Brief in Opposition, as well as identify matters asserted by Zoecon in its Counter-Statement of the case which are wholly outside the record of this case and are therefore improper for consideration by this Court.

of whether the Federal Insecticide Fungicide and Rodenticide Act, 7 U.S.C. §136, *et. seq.* ("FIFRA") preempts state common law based failure to warn claims. Zoecon also concedes that the question of FIFRA's preemptive effect is an important federal question, and acknowledges that the court of appeals decision in this case failed to address the presumption against federal preemption.

Because the legal issues presented by this case are so well-crystalized and ripe for decision, this Court should grant certiorari in order to resolve the conflict and answer the important questions of federal law presented. Alternatively, as Petitioners have suggested, the Court should hold the instant petition in abeyance pending resolution of *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3rd Cir. 1986), 893 F.2d 541 (3rd Cir. 1990), *cert. granted,* 111 S.Ct. 386 (1991).

ARGUMENT

A. ZEOCON CONCEDES THAT THERE IS A DIRECT SPLIT IN THE CIRCUITS ON THE ISSUES PRESENTED BY THIS CASE.

Zoecon's first argument in opposition to certiorari is its illogical and unjustified assertion that this Court should not resolve the clear split of authority between the District of Columbia Court of Appeals and the Eleventh Circuit Court of Appeals on the very question presented by this litigation. Although Zoecon acknowledges that there is a direct conflict between the circuits, which have had occasion to decide the question, and that there is a tremendous split of authority in the lower and state courts (*see,* Brief In Opposition at p. 13), it nevertheless contends that certiorari should not be granted because there is not, in Zoecon's view, a sufficient number of court of appeals decisions on the subject. This argument completely ignores the fact that there is no consistency whatsoever in the federal law regarding the

question of FIFRA preemption, as the ruling and opinion in *Papas v. Upjohn Co.* 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed,* 59 U.S.L.W. 3825 (U.S. Apr. 29, 1991) (No. 90-1837), is diametrically opposed to the ruling and opinion in *Ferebee v. Chevron Chemical Co.,* 736 F.2d 1529 (D.C. Cir. 1984) *cert. denied,* 469 U.S. 1062 (1984). Despite its full recognition of this irreconcilable conflict, Zoecon would nevertheless have this Court overlook it, suggesting that somehow the authority is lopsided in favor of preemption, even though Zoecon acknowledges the vast split of authority on the question in the lower courts. Contrary to Zoecon's contention, lower court cases are not coming down clearly in favor of one rationale over the other, and the conflict only becomes more irreconcilable.[2]

Realizing the futility of these contentions, Zoecon then attempts to argue that other Supreme Court opinions have reduced *Ferebee's* credibility, citing *International Paper Co. v. Ouellette,* 479 U.S. 481 (1987) and *Ingersoll Rand Co. v. McLendon,* 111 S.Ct. 478 (1990), for this erroneous proposition. Zoecon's reliance on these cases is misplaced, as it fails to recognize the significant distinctions between the matters considered in *International Paper Co.,* and *Ingersoll Rand,* and the questions presented by the instant case. *International Paper Co.,* concerned the Clean Water Act, 15 U.S.C. §1251 *et seq.,* which has a regulatory scheme wholly distinguishable from that established in FIFRA. The preemption ruling in *International Paper, Co.,* unlike the court of appeals' decision in the case at bar, did not leave the aggrieved party without any remedy whatsoever for the alleged wrong, as the Court noted:

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[2]Yet another district court has recently ruled that FIFRA does not preempt state law based claims of failure to warn. *See, Riden v. ICI Americas, Inc.,* No. 89-0903-CV-W-1 (W.D. Mo. May 14, 1991).

> Our conclusion that Vermont nuisance law is inapplicable to a New York point source does not leave respondent without a remedy. The CWA precludes only those suits that may require standards of effluent control that are incompatible with those established by the procedures set forth in the Act. The savings clause specifically preserves other state actions, and therefore nothing in the Act bars aggrieved individuals from bringing a nuisance claim pursuant to the law of the *source* state. *Id.* at 497

Ingersoll Rand, concerned the Employment Retirement Income Security Act's, 29 U.S.C. §301 *et seq.* ("ERISA"), express preemption of a state law based claim, and in so doing recognized that the plaintiff in that case had an appropriate remedy under ERISA with respect to his pension benefits, the very subject of the act. Neither of the cases cited involved regulatory schemes like FIFRA, where the relevant federal agency regulates products and their warning labels, based upon information submitted by their manufacturers who seek approval. Further, the result in those cases was not that an injured party would be left with no remedy for the wrong perpetrated.

Again acknowledging the vast split in authority on the question presented, Zoecon then suggests that this Court should not grant certiorari because, in Zoecon's opinion, other courts of appeals considering the question of FIFRA preemption will undoubtedly adopt the rationale of *Papas, supra.* This "wait and see" position advocated by Zoecon simply invites greater inconsistency and manifest injustice throughout the federal and state court systems. *See, Beaulieu v. United States,* 893 F.2d 1177 (10th Cir. 1989), *cert. denied,* 110 S.Ct. 3302 (1990), White, J. *dissenting.* The conflict in rulings regarding FIFRA preemption will continue to exist, and will not simply evaporate into thin air as Zoecon would have the court believe.

Moreover, Zoecon's one-sided view completely ignores that

courts throughout the nation are not being persuaded that the *Papas* rationale for finding FIFRA preemption is legally correct. For example, the Supreme Court of New Jersey in *Feldman v. Lederele Laboratories*, No. A-93, (N.J. July 24, 1991), has questioned the Eleventh Circuit's decision in *Papas, supra*. In conducting an implied preemption analysis in an FDA product case, the New Jersey Supreme Court stated:

> The split among courts addressing the issue suggests that there is not a "clear and manifest" expression of congressional intent and calls into question the reasoning and authority of *Papas*. *Id.* at 32.

Similarly, Zoecon's argument escapes notice that this Court's opinion in *Wisconsin Public Intervenor v. Mortier*, 115 L.Ed.2d 532 (1991) recognized that FIFRA was not so comprehensive a regulatory scheme that Congress had totally occupied the field of pesticide regulation so as to completely preclude any augmentation or supplement to the subject. *Id.* at 539. It is clear that the issues presented by this case are ripe for determination by this Court and Zoecon's suggestion to deny certiorari would only fuel the fires of the FIFRA preemption controversy raging throughout the lower courts.

B. ZOECON DOES NOT DISPUTE THAT THE COURT OF APPEALS DECISION IGNORES THE PRESUMPTION AGAINST PREEMPTION.

Zoecon does not truly take exception with the Petitioners' observation that the Eleventh Circuit in the case at bar ignored the presumption against preemption, (*see*, Brief In Opposition at p. 19), as in that court's view the presumption simply does not apply. It nevertheless asserts that the Eleventh Circuit's ignoring the presumption is of no matter, because that court made findings sufficient to overcome the presumption. Zoecon's argument simply glosses over this fallacy

in the Eleventh Circuit's reasoning. As a matter of federal law and this Court's precedents, the presumption against preemption is significant and must always apply. *Maryland v. Louisiana*, 451 U.S. 725 (1981). Improperly ignoring the mandatory presumption against preemption made the Eleventh Circuit's decision finding implied preemption far easier than had it applied the correct presumption. Likewise, Zoecon's contention that the Petitioner's state law tort claims do not involve indirect or incidental regulatory pressure as opposed to direct pressure, is completely at odds with the established law that the presumption against preemption is even greater where state common law claims at issue do not give rise to direct interference with federal regulations, as is created by direct contradicting state regulations. *See, English v. General Electric Co.*, 110 S.Ct. 2270 (1990); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988) and *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

The court of appeals in the instant case completely ignored the presumption against preemption, in keeping with its pronounced view that the presumption does not apply to implied preemption analysis. Because that view is directly contrary to this Court's and other circuit court's decisions on a critically important point of federal law, certiorari should be granted for this reason alone.

C. ZOECON DOES NOT DISPUTE THAT WHETHER CONGRESS INTENDED FIFRA TO PREEMPT PLAINTIFFS' STATE COMMON LAW WARNING CLAIMS IS AN IMPORTANT FEDERAL QUESTION.

Zoecon's Brief in Opposition does not take issue with our contention that the issues presented by this case are significant questions of federal law with far reaching impact. Instead, Zoecon merely asserts that the court of appeals correctly decided these controversial

questions. The decision in *Ferebee, supra,* however, demonstrates otherwise. Moreover, the arguments advancing Zoecon's brief only make it plain that this court's review is necessary. The critically important federal question presented by this case - whether Congress intended FIFRA to preempt common law claims - will not go away. The question should be decided by this court in this case.

Apparently driven by concerns about the extraordinary facts of this case; i.e.: the EPA and FDA approving Paramite's label without knowing that Paramite contains benzene, and the Eleventh Circuit then holding that the EPA's approval of the label preempts Plaintiffs' claims, when the Fifth Circuit had already held in similar circumstances that FDA approval does not, Zoecon takes extraordinary steps in regards to the facts. First it makes several inaccurate factual representations in its Counter-Statement of the Case[3]. It also blatantly presents facts

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[3]For example, Zoecon in its brief at page 8, for the first time in the case, asserts that Petitioners incorrectly represent that Paramite was approved by both EPA and the Food and Drug Administration ("FDA") pursuant to the Federal Drug and Cosmetic Act, 21 U.S.C. §301 et. seq. ("FDCA"), as a new animal drug. The record below includes the following deposition testimony of Sally A. Jaksa, Zoecon's Manager of Regulatory Affairs:

Q: Ok. Are you familiar with when the Paramite product was approved by any governmental agency?

A: Generally, yes.

Q: Ok, could you tell me about when that was.

A: When? Late seventies. I think.

Q: Ok. And do you know which governmental agencies approved the Paramite formula product?

A: Well, initially it was FDA and then EPA and I don't know which was first.

Q: Initially FDA?

A: Uh-huh.

Q: Do you know why this product would be looked at by both FDA and EPA?

A: It is an FDA product because it controls an internal parasite, grubs.

Q: Was a new - new drug application filed with the FDA?

A: Yes.

Transcript of oral deposition of Sally A. Jaksa taken February 3, 1989 at p. 18.

wholly outside the record[4]. Both of these steps are taken to bolster Zoecon's weak argument.

That is why this Court need decide whether a manufacturer who submits inaccurate or incomplete information to the EPA is immune from suits for injuries caused by the resultant inadequate warnings, even if FIFRA ordinarily preempts warning claims.

Zoecon essentially concedes that the holding in *Hurley v. Lederele Laboratories*, 863 F.2d 1173 (5th Cir. 1988), also conflicts with the court of appeals decision in *Papas, supra*. In *Hurley*, the Fifth Circuit, considering the preemptive effect of the FDCA, reasoned that preemption could occur only where the FDA had processed all of the

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Similarly, Zoecon claims that benzene is an impurity in Paramite's inert ingredient, as opposed to the inert itself, and that somehow this is of significance. In fact however, the significant point is that harmful benzene is always present in Sure Sol 190, (the inert ingredient comprising 75% of Paramite) in toxicologically significant amounts, approximately 1/10 of 1% benzene by weight according to Sure Sol 190's manufacturer. However the benzene is classified is of no matter and is simply an argument over semantics.

[4]For example, Zoecon's factual assertions at page 10 of its brief that, as a result of the Petitioners' allegations, Zoecon determined Paramite's benzene content and informed EPA, which determined an additional warning was not required, is completely outside the record in this case. It is also at odds with Zoecon's position in this litigation, that Paramite and its inert Sure Sol 190 do not contain benzene to Zoecon's knowledge. Moreover, even if Zoecon's assertions were true, they would only lend credence to the Petitioners' claims that EPA's regulation of pesticides is woefully deficient.

Likewise, Zoecon's argument concerning the Petitioners' filing a separate suit against Sure Sol 190's manufacturer is misleading, particularly with regards to the availability of an alternative remedy. Petitioners attempted to add the manufacturer to the litigation, but the district court did not permit the joinder, because in its view the claims against the manufacturer of Sure Sol 190 included failure to warn claims that are likely preempted (*see* Pet. App. p. 25). The separate suit was filed to avoid the arguable running of the statute of limitations and the suit has also been stayed by the same district judge presiding over this case, pending the instant appellate proceedings' resolution.

relevant and available information on which to base the warning in question. *Id.* at 1179.

Zoecon's argument that the holding in *Hurley*, should not affect the outcome of this case is premised on two flawed contentions. First, Zoecon contends that the Petitioners' analogy between the FDCA and FIFRA is in error because whereas the FDA is a "partially passive agency," the EPA's role under FIFRA, according to Zoecon, is different. This assertion is completely incorrect. Under the statutory scheme of FIFRA, the EPA, like the FDA under the FDCA, specifies what data must be submitted, reviews the data submitted by manufacturers, and then approves or disapproves the warning label submitted. By statute and/or the applicable regulations, the EPA is no more active an agency than the FDA in this regard. The role EPA plays under FIFRA is certainly no greater than the role the FDA plays in considering products for approval and their warnings under the FDCA.

Petitioners pointed out to the court of appeals that it makes no sense that Zoecon would be insulated from liability for inadequate warnings associated with the Paramite product when that product was approved both by the FDA and the EPA, especially when Upjohn's similar FDA product would not enjoy such an immunity.

Petitioners also pointed out that, even if FIFRA ordinarily preempts failure to warn claims, because Zoecon submitted inadequate or inaccurate data concerning Paramite to EPA, that under the *Hurley, supra*, rationale, there should be no preemption.

Zoecon, by incorrectly asserting that Paramite was never approved by FDA, attempts to somehow distinguish the situation in *Hurley* (an FDA case) from the instant case, without any basis for such a distinction. The record in the case indicates the Paramite product was approved by both agencies, and also clearly establishes that Zoecon never informed EPA of Paramite's benzene content. In fact, Zoecon had

insisted throughout this litigation, until it filed its Brief In Opposition, that Paramite contained no benzene whatsoever (*see*, note 4, *infra*). Accordingly, the extant facts in this case are ideal for this Court to decide whether or not the *Hurley, supra,* "exception" to preemption is applicable law.

The *Hurley* rationale certainly makes sense. Before a warning label approved by a federal agency can properly be the basis of preemption, it is imperative that the agency (unlike in this case) receive accurate and complete data necessary for making such a decision. Because manufacturers are solely responsible for providing the information to the agency, if incomplete or inaccurate data results in a deficient warning, there should be no immunity from state law claims because, as in this case, the injury would largely be the fault of the manufacturer. Absent the *Hurley* "exception", manufacturers whose products injure consumers would never be required to answer for such injuries.

This case presents the factual scenario whereby the relevant agency was not provided with accurate or adequate information when it registered the product and approved its warning labels. This Court should also grant certiorari in order to determine whether state common law based tort claims are preempted by FIFRA under such conditions.

D. ZOECON'S ARGUMENT THAT THE DECISION IN *CIPOLLONE V. LIGGETT GROUP, INC.* WILL NECESSARILY HAVE NO IMPACT ON THIS CASE IS ERRONEOUS.

As pointed out in the Petition, because this Court has granted certiorari in *Cipollone v. Liggett Group, Inc., supra,* and in that

Cipollone involves similar issues relative to a preemption analysis, should this Court not grant certiorari outright in this case, it should nevertheless hold the instant Petition in abeyance pending resolution of *Cipollone*. It is hypocritical for Zoecon to suggest that the distinctions between FIFRA and the Federal Cigarette Labeling and Advertising Act 15 U.S.C. §1331 *et. seq.* (the "Cigarette Act"), at issue in *Cipollone*, mitigate against holding the instant Petition in abeyance. As Petitioners have pointed out, pesticide manufacturers, including Zoecon in this very case, began to raise the preemption defense after *Ferebee, supra*, had seemingly resolved the issue, when the defense found favor in certain cases involving the Cigarette Act. In fact, decisions in Cigarette Act cases served as the preeminent and often only judicial authority cited by courts to support a finding of FIFRA preemption. *See, e.g. Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D.Mich. 1987).

Because it is clear that the argument supporting FIFRA preemption of pesticide warning claims is far less compelling than the argument for express preemption asserted in Cigarette Act cases, it is certainly logical that, at a minimum, the instant Petition should be held in abeyance. Undoubtedly, this Court will also address in detail the presumption against preemption in resolving *Cipollone*, which will significantly impact any decision in the case at bar. The fact that Zoecon has opposed certiorari as well as abeyance pending the outcome of *Cipollone*, despite the unquestionable split of authority existing in the courts on the issue of FIFRA preemption, is indicative that Zoecon genuinely fears that if this Court reviews this case, it will appropriately rule that FIFRA does not preempt common law warning claims, such as those brought by the Petitioners.

CONCLUSION

For the foregoing reasons, the Petition For A Writ of Certiorari should be granted. In the alternative, this Court should hold the instant Petition in abeyance, pending the resolution of *Cipollone v. Ligget Group, Inc.*

Respectfully submitted,

Dana G. Bradford II
(Counsel of Record)
Lee S. Haramis
BAUMER, BRADFORD, WATERS
& LILES, P.A.
Suite 2000
One Enterprise Center
225 Water Street
Jacksonville, FL 32201
904/358-2222

Arthur H. Bryant
TRIAL LAWYERS FOR
PUBLIC JUSTICE, P.C.
1625 Massachusetts Ave., NW
Suite 100
Washington, D.C. 20036
202/797-8600

Attorneys for Petitioners

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